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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

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JOHN S. PRATT, ESQ  
KILPATRICK STOCKTON, LLP  
1100 PEACHTREE STREET  
ATLANTA, GA 30309

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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07/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,489	<b>Applicant(s)</b> DREWE ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,8-12,18,19 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8-12,18,19 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. The Applicants' response to the office action field on May 08, 2008 has been considered and acknowledged.

***Status of the application***

2. Currently claims 1-2, 5-6, 8-12, 18-19, 22-26 are pending under examination. Claims 3-4, 7, 13-17, 20-21 are cancelled. Applicants' arguments and the amendment have been fully considered and deemed unpersuasive for the reasons that follow.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-6, 8-12, 18-19, 22-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of "contacting the sample during the amplification with a peptide nucleic acid" in the claims 1, 6, 18, 25 appears to represent new matter. A careful review by examiner of the specification this limitation was not present. The specification on page 3, line 31-34 and page 4, line 1-12 indicates that the purine rich region is introduced into the target

sequence during amplification, however, the specification lacks descriptive support for contacting the target sample with a peptide nucleic acid during the amplification. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

***Response to Arguments:***

4. With regard to the rejection of claims 1-2, 5-6, 8, 12, 22, 24 under 35 USC 102(b) as being anticipated by Orum et al., Applicants' arguments and amendment were fully considered and found unpersuasive. First, the amendment did not change the scope of the claims, since the PNA binds to a target comprising purine-rich sequence. Second, Orum et al. teach use of a PNA primer to compete with PCR primer to block the PCR amplification (no signal) or selective amplification of perfectly matched PCR primer (presence of signal). Further Orum et al. does teach PNA binding with the target nucleic acid comprising purine-rich sequence when the PNA is complementary to the target sequence located at a distance from the PCR primers. Fig. 7 of the Orum et al. reference clearly indicates the presence of the signal with PNA binding to the target nucleic acid comprising purine-rich sequence. In addition, with regard to the Applicants' arguments based on the amendment reciting 'contacting PNA that is able to bind to the target comprising purine-rich sequence', it is noted that the claims do not necessarily read on the binding of PNA to a purine-rich sequence introduced by the primers, rather PNA can bind to the purine-rich sequence else where in the target sequence located between the PCR primers, which is clearly demonstrated in Orum et al. reference (Fig.7). Accordingly the arguments were found unpersuasive and the rejection is maintained.

5. With regard to the rejection of claims 9-11, 18-19, 23, 25-26 under 35 USC 103(a) as being unpatentable over Orum et al. in view of Graham et al., Applicants' arguments and amendment were fully considered and found unpersuasive. As discussed above Orum et al. does teach PNA binding during PCR and detection of the presence of signal, And as discussed in the rejection, it is obvious to modify the method of Orum et al. with waveguide as taught by Graham et al. as discussed in the rejection. Accordingly the rejection is maintained.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

Application/Control Number: 09/744,489  
Art Unit: 1637

Page 5